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| APPLICATION NO. | FILING DATE FIRST NAMED INVENTOR | | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
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| 09/692,245 | 10/19/2000 | Harry F. Prest | 10003375-1 | 6797 | |
| 22878 | 7590 09/13/2002 | | | | |
| AGILENT TECHNOLOGIES, INC. INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT. P.O. BOX 7599 | | | EXAMINER | | |
| | | | LUDLOW, JAN M | | |
| M/S DL429 LOVELAND | , CO 80537-0599 | ART UNIT | PAPER NUMBER | | |
| | , | | 1743 | 4 | |
| | | DATE MAILED: 09/13/2002 | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.



| Office Action Summary Examiner | | | | <u>-</u> | | MK-L | | | | |
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| ## Defice Action Summary - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH (S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filled after Si (6, MONTHS from the maining date of files communication. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filled after Si (6, MONTHS from the maining date of the communication. If NO period for reply is specified above, the maximum leathers by predict vill apply and will expire SiX (6) MONTHS from the maining date of the communication. Failube to reply within the set or caredade period for reply will, by statule, use the application become PANN-DONE (36 U.S. C) and status as the second period for reply will be status as the second period for reply will be status as a second period for reply will be status as a second period for reply will be status as a second period for reply will be status. 1) □ Responsive to communication(s) filed on | • | | Application N | ١. | Applicant(s) | | | | | |
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| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MALLING DATE OF THIS COMMUNICATION. Estimations of time may be available under the provisions of 31 CRR 1.138(a). In no event, however, may a reply be timely flied Estimations of times may be available under the provisions of 31 CRR 1.138(a). In no event, however, may a reply be timely flied If the period for reply specified above, the maximum statutory period vitil apply and vall expire \$1X\$ (b) MONTHS from the malling date of this communication of reply specified above, the maximum statutory period vitil apply and vall expire \$1X\$ (b) MONTHS from the maling date of this communication of the provision of the provis | | | l l | | | | | | | |
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| 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | pplication). | | | | |
| Attachment(s) | 15)[] A | cknowledgment is made of a claim for domesti | • • | | | | | | | |
| | _ | | _ | _ | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 . 4) Interview Summary (PTO-413) Paper No(s) 5) Notice of Informal Patent Application (PTO-152) 6) Other: | 2) Notice | of Draftsperson's Patent Drawing Review (PTO-948) | 5) [| Notice of Informal P | | | | | | |

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenfeld.

Rosenfeld teaches a method of analyzing prostaglandin E2 (PGE2) using PFBBr and PFBHOX derivatizing agents in situ on a column. Samples are then subjected to gas chromatography and electron capture and the trace shown in Figure 8. Two peaks are labeled PGE2, indicating that two derivatives are present. It is the examiner's position that the X-axis on the chromatographic trace is time because the beginning and

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end of the axis are labeled "start" and "stop" which indicate reference to time. See Example 16. Rosenfeld additionally teaches separation of derivatives of THC formed metabolically and further derivatized in situ (Figures 4A-4B).

- 5. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld.
- 6. Rosenfeld additionally teaches that Mass Spec analysis can be used in place of Electron Capture (EC) in the PGE2 analysis (col. 19, lines 25-26) and that MS typically includes negative ion chemical ionization mode (col. 1, lines 25-30).
- 7. Rosenfeld fails to explicitly teach determining retention times, ionizing derivatized anlaytes or mass spec using negative chemical ionization for the PGE2 or THC analyses.
- 8. With respect to the alternative rejection, if it is applicant's position that Rosenfeld does not determine retention times, it would have been obvious to determine retention times in order to identify peaks as shown in the Figures and as was known in the art. It would have been obvious to ionize the derivatized analytes in order to perform EC, Mass Spec or Mass Spec with negative ion chemical ionization mode in order to perform the analyses taught or suggested by Rosenfeld for detecting and quantifying the derivatized analytes. It is the examiner's position that prostaglandin constitutes a drug of abuse because it is a hormone-like substance that may be used improperly. With respect to specific drugs of abuse other than THC and prostaglandin, and derivatizing agents other than those disclosed by Rosenfeld, Rosenfeld teaches that the method is widely applicable to drug, herbicide and pesticide residues (col. 7, lines 28-

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32) and it would have been obvious to perform the method on the claimed classes of

compounds as known drugs, using known classes of derivatizing agents.

9. The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure.

10. Apffel additionally teaches dual derivatizing agents in a detection method.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-

4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00

pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers

for the organization where this application or proceeding is assigned are (703) 872-9310

for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is (703) 308-

0661.

Jan M. Ludlow

Primary Examiner

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September 11, 2002